Supreme Court, U.S.
FILED
MAR 13 1996
CLERK

(18) (19)

Nos. 95-754 and 95-886

IN THE

Supreme Court of the United States

OCTOBER TERM, 1995

MEDTRONIC, INC.,
Petitioner/Cross-Respondent,

v.

LORA LOHR AND MICHAEL LOHR,
Respondents/Cross-Petitioners.

On Writs of Certiorari
to the United States Court of Appeals
for the Eleventh Circuit

BRIEF *AMICI CURIAE* OF AMERICAN ASSOCIATION OF RETIRED PERSONS, CONSUMERS UNION, CONSUMER FEDERATION OF AMERICA, NATIONAL WOMEN'S HEALTH NETWORK, COMMAND TRUST NETWORK AND VALV IN SUPPORT OF RESPONDENTS/CROSS-PETITIONERS LORA LOHR AND MICHAEL LOHR

DAVID HALPERIN
Counsel of Record
2027 Massachusetts Avenue, NW
Washington, D.C. 20036
(202) 328-2232

Counsel for *Amici Curiae*

March 13, 1996

40pp

TABLE OF CONTENTS

STATEMENT OF INTEREST 1

SUMMARY OF ARGUMENT 1

ARGUMENT 3

I. THE VAGUE PREEMPTION PROVISION IN THE MEDICAL DEVICE AMENDMENTS CANNOT OVERCOME THE STRONG PRESUMPTION AGAINST PREEMPTING THE TYPE OF STATE LAW AT ISSUE HERE 3

II. THE LIMITED POWERS THE MDA CONFERRED ON THE FOOD AND DRUG ADMINISTRATION INDICATE THAT CONGRESS DID NOT MEAN TO PREEMPT STATE LAW TORT ACTIONS 6

A. The Primary Purpose of the MDA Was to Enhance Protection of Public Health and Safety 6

B. Federal Authority Under the MDA Did Not and Does Not Provide For Many of the Means of Protection Available Through the Tort System 7

1. Limits on Scrutiny of Medical Devices 8

2. Limits on FDA Enforcement Authority 13

3. Lack of Damage Remedies 16

C. Inadequate Funding of the FDA from the 94th Congress to the Present Has Further Weakened the Capacity of the Agency to Ensure Health and Safety 18

III. THE MANY CASES OF SEVERE INJURY CAUSED BY MEDICAL DEVICES SINCE 1976 SHOW THE LIMITED NATURE OF THE FDA'S AUTHORITY AND UNDERSCORE THAT CONGRESS DID NOT MEAN TO PREEMPT STATE TORT SUITS 20

A. The Tort System Has Functioned As Congress Envisioned When It Passed the MDA: As a Necessary Complement To Federal Authority 20

B. The Bjork-Shiley Heart Valve 21

C. The Vitek Jaw Implant 23

D. Playtex Super-Absorbent Tampons 23

E. The Airco Ventilator 24

F. Orcolon Eye Gel 24

G. Silicone Breast Implants 25

H. Pedicle Screws 26

IV. A FINDING OF PREEMPTION HERE WOULD OPEN THE FLOODGATES FOR DEMANDS FOR JUDICIALLY-CREATED TORT IMMUNITY . . 27

CONCLUSION 29

TABLE OF AUTHORITIES

CASES **Page**

Airco, Inc. v. Simmons First National Bank,
638 S.W.2d 660 (Ark. 1982) 24

Bailey v. Johnson,
48 F.3d 965 (6th Cir. 1995) 16

Bowling v. Pfizer,
143 F.R.D. 141 (S.D. Ohio 1992) 22

Cipollone v. Liggett Group, Inc.,
505 U.S. 504 (1992) 17, 27

Duvall v. Bristol-Myers-Squibb Co.,
65 F.3d 392 (4th Cir. 1995),
petition for cert. filed,
Dec. 22, 1995, No. 95-1010 27

English v. General Electric Co.,
496 U.S. 72 (1990) 5

English v. Mentor Corp.,
67 F.3d 477 (3d Cir. 1995),
petition for cert. filed,
Dec. 26, 1995, No. 95-1034 27

Hawaiian Airlines, Inc. v. Norris,
114 S. Ct. 2239 (1994) 4

Hillsborough County v. Automated Medical Laboratories,
471 U.S. 707 (1985) 5

King v. Collagen Corp.,
983 F.2d 1130 (1st Cir.),
cert. denied, 114 S. Ct. 84 (1993) 27

Maryland v. Louisiana,
451 U.S. 725 (1981) 5

Michael v. Shiley, 46 F.3d 1316 (3rd Cir. 1995),
cert. denied, 116 S. Ct. 67 (1995) 22

Moe v. MTD Products, Inc.,
73 F.3d 179 (8th Cir. 1995) 29

Moore v. Kimberly-Clark Corp.,
867 F.2d 243 (5th Cir. 1989) 15

New York Telephone Co. v. New York State Department of Labor,
440 U.S. 519 (1979) 5

O'Gilvie v. International Playtex, Inc.,
821 F.2d 1438 (10th Cir. 1987),
cert. denied, 486 U.S. 1032 (1988) 23

In Re: Orthopedic Bone Screw Product Liability Litigation,
M.D.L. Docket No. 1014 (E.D.Pa.) 26

Silkwood v. Kerr-McGee Corp.,
464 U.S. 238 (1984) 5, 16

Slater v. Optical Radiation Corp.,
961 F.2d 1330 (7th Cir.),
cert. denied, 113 S. Ct. 327 (1992) 15

Stamps v. Collagen Corp.,
984 F.2d 1416 (5th Cir.),
cert. denied, 114 S. Ct. 86 (1993) 27

Talbott v. C.R. Bard, Inc.,
865 F. Supp. 37 (D.Mass. 1994),
aff'd, 63 F.3d 25 (1st Cir. 1995),
petition for cert. filed,
Feb. 16, 1996, No. 95-1321 11

United States v. C.R. Bard, Inc.,
848 F. Supp. 287 (D. Mass. 1994) 10

CONSTITUTIONAL PROVISIONS, STATUTES & REGULATIONS

Consumer Product Safety Act,
15 U.S.C. § 2075 28

Federal Hazardous Substances Act,
15 U.S.C. § 1261 note 28

Federal Rule of Civil Procedure 26(b)(1) 13

Federal Rule of Civil Procedure 37 13

Medical Device Amendments of 1976,
P.L. No. 94-295, 90 Stat. 539 (1976)
(codified at 21 U.S.C. § 360c *et seq.*) . . . . . *passim*

21 U.S.C. § 351(f)(2)(B) 11

21 U.S.C. § 360c(f)(1) 12

21 U.S.C. § 360e(b)(1)(A) 11

21 U.S.C. § 360e(c)(1) 9

21 U.S.C. § 360e(c)(2) 9

21 U.S.C. § 360h(b)(1) 13

21 U.S.C. § 360j(h)(1) 9

21 U.S.C. § 360j(i) 9

21 U.S.C. §360k(a) 4, 28

Safe Medical Devices Act of 1990,
P.L. No. 101-629, 104 Stat. 4511 . . . . . 9, 14

21 U.S.C. § 333(g)(1)(A) 14

21 U.S.C. § 333(g)(2)(A) 14

21 U.S.C. § 360h(e) 14

21 U.S.C. § 360h(e)(1)(A) 14

21 U.S.C. § 360h(e)(1)(B) 14

21 U.S.C. § 360*l* 14

U.S. Const. art. VI, cl. 2 4

21 C.F.R. § 807.100 (b) 12

LEGISLATIVE MATERIALS

121 Cong. Rec. 10688 (1975) 7

141 Cong. Rec. H2941 (Mar. 9, 1995) 4

141 Cong. Rec. H3027 (Mar. 10, 1995) 4

H.R. Conf. Rep. No. 1090, 94th Cong., 2d Sess. (1976) . . . 7

H.R. Rep. 808, 101st Cong., 2d Sess.,
reprinted in 1990 U.S.C.C.A.N. 6307 12

H.R. Rep. 853, 94th Cong., 2d Sess. (1976) 6, 7

Staff of Subcomm. on Oversight and Investigations, Comm. on Energy and Commerce, *The Bjork-Shiley Heart Valve: "Earn As You Learn"; Shiley Inc.'s Breach of the Honor System and FDA's Failure in Medical Device Regulation*, Comm. Print 101-R, 101st Cong., 2d Sess. (1990) 14, 22

Subcomm. on Oversight and Investigations, Comm. on Energy and Commerce, *Less Than the Sum of Its Parts; Reforms Needed in the Organization, Management, and Resources of the Food and Drug Administration's Center for Devices and Radiological Health*, Comm. Print 103-N, 103d Cong., 1st Sess. (1993) 18, 21, 25

Testimony of FDA Commissioner David A. Kessler before the Senate Comm. on Labor and Human Resources, Apr. 6, 1995 . . . . . 12, 18

Testimony of FDA Commissioner David A. Kessler before the House Subcomm. on Human Resources and Intergovernmental Relations, Comm. on Government Reform and Oversight, Aug. 1, 1995 25

Testimony of J. Robert Hunter before the Subcomm. on Admin. Oversight and the Courts of the Senate Comm. on the Judiciary, May 2, 1995 8

MISCELLANEOUS

Adler, *The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction*, 43 Food Drug Cosm. L.J. 511 (1988) 13, 14, 18

Adler & Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895 (1994) 7

Bates, *TSS Award Slashed After Playtex Stops Selling Tampon*, The National Law Journal, June 10, 1985, at 10 24

Boston Globe, Apr. 2, 1994, Economy, at 12 10

Boston Globe, Oct. 31, 1993, Metro/Region, at 1 10

Boston Globe, June 5, 1992, ... 11 23

Connelly, *Jaw Implant Suit Takes the Fast Track*, Texas Lawyer, July 17, 1995, at 6 23

Cooper, *Device Legislation*, 26 Food Drug Cosm. L.J. 165 (1971) 6

Frankel, *From Pioneers to Profits*, The American Lawyer, June 1992, at 82 26

Green, *Dangerous Devices; Artificial Implants*, American Health, Jan. 1995, at 68 . . . . . 22, 25

Hoffman, *Medical Device Liability Case; High Courts Ruling Likely to be Pivotal*, Business Insurance, Jan. 29, 1996, at 2 4

Hunter, *Product Liability Insurance Experience 1984-1993* (Consumer Federation of America, Mar. 1995) 8

Johnson, et. al, Report of the Shiley Task Group (Dec. 1990) 21

Leflar, *Public Accountability and Medical Device Regulation*, 2 Harv. J.L. & Tech. 1 (1989) 9, 12, 13

MacLachan, *Bone Screw Suit Places FDA in 4-Way Squeeze*, The National Law Journal, Jan. 8, 1996, at A1 27

N.Y. Times, June 5, 1992, at A14 23

N.Y. Times, Aug. 1, 1984, at D1 16

N.Y. Times, Aug. 8, 1982, sec. 4, at 7 18

Nightline (ABC television broadcast, Aug. 17, 1995) 25

U.S. General Accounting Office, *Medical Technology: Quality Assurance Needs Stronger Management Emphasis and Higher Priority* (GAO/PEMD-92-10 Feb. 1992) 19

Wall Street Journal, Dec. 11, 1995, at B5 8

Washington Post, Feb. 28, 1996, at A13 25

Washington Post, Mar. 3, 1992, at Z10 26

Washington Post, Apr. 7, 1985, at A1 16

STATEMENT OF INTEREST

With the written consent of the parties, reflected in letters on file with the Clerk, the American Association of Retired Persons, Consumers Union, Consumer Federation of America, the National Women's Health Network, Command Trust Network, and VALV respectfully submit this brief as *amici curiae*, pursuant to Rule 37 of the Rules of this Court.

Amici are non-profit organizations concerned with public health and safety. Each believes that the public cannot be adequately protected against dangerous medical devices in the absence of effective state law tort remedies.

The American Association of Retired Persons is a membership organization of 33 million persons age 50 and over; it seeks to enhance the quality of life for older persons by promoting independence, dignity and purpose; sponsors research on aging; provides educational programs, publications, volunteer opportunities and member benefits; and represents the concerns of older Americans before government bodies. Consumers Union is a membership organization, chartered in 1936, which provides consumers with information, education and counsel about goods, services, health and personal finance; initiates and cooperates with individual and group efforts to maintain and enhance the quality of life for consumers; and publishes *Consumer Reports* magazine, with paid circulation of approximately 5 million. Consumer Federation of America is an association of some 240 pro-consumer groups, with a combined membership of 50 million people; it was founded in 1968 to advance the consumer interest through advocacy and education. The National Women's Health Network is a membership group which advocates for better federal health policies for women and works to ensure that safe drugs, devices and medical procedures are available to all women; it is supported by 15,000 individual and 300 organizational members representing over 500,000 people. Command Trust Network is an international informational clearinghouse for women who have questions about breast implants. VALV is a support group for recipients of the Bjork-Shiley convexo-concave heart valve. *See* part III.B, *infra*.

SUMMARY OF ARGUMENT

Medtronic, Inc., asks this Court to hold, based on the vague preemption provision in the Medical Device Amendments of 1976,

P.L. No. 94-295, 90 Stat. 539 (1976) (codified at 21 U.S.C. § 360c *et seq.*) ("MDA" or "the Act"), that Congress meant to grant manufacturers immunity from state tort liability with respect to medical devices. If this Court is to remain faithful to long-standing principles of federalism and separation of powers, it must reject this utterly implausible proposition, aimed, as one industry representative has put it, at obtaining "tort reform" from the bench "without a single vote from this Congress." Had the 94th Congress in 1976 truly sought to effect the radical transformation of the law claimed by Medtronic — and to do so in an apparently arbitrary way, affecting some products (medical devices), though not others (such as food and drugs) — surely it would have debated the issue and explained its bold step, just as intense discussion surrounds "tort reform" proposals in Congress today. But there is no evidence of any such debate or remarks in 1976, because there was never any such intention.

In fact, Congress's clear goal in enacting the MDA was not to "reform" tort law to suit industry but rather to enhance protection of public health and safety. Congress crafted a limited regulatory regime that could only have been effective in achieving that goal if it was a complement to — not a substitute for — state tort remedies.

The MDA was and is wholly inadequate as a replacement for tort law. The MDA does not provide the Food and Drug Administration ("FDA") with sufficient means and incentives to obtain information about medical devices and their manufacturers, either before or after devices go on the market. Nor does the MDA provide damages for people injured by dangerous devices. Nor, as enacted in 1976, did the Act provide for civil penalties to punish violators or give the FDA sufficient authority to force the recall of harmful devices. In addition, the MDA includes mechanisms — the so-called grandfathering and substantial equivalence provisions — permitting the sale of devices never examined by the federal government for safety or effectiveness — and about 99 percent of medical devices enter the market through these procedures. In sharp contrast, tort law provides broad discovery provisions that bring to light important product information; damages awards to deter and compensate for wrongful acts, as well as injunctive relief to stop them; and a mechanism by

which state authority may evaluate the safety and effectiveness of *any* medical device used on patients.

The Congress that enacted the MDA, as well as every subsequent Congress, has failed to fund the FDA at a level that might have permitted the agency to make adequate use of even the limited statutory powers it has. These funding decisions are further evidence that Congress never intended that FDA oversight would entirely supplant the tort system in dealing with medical devices.

The many deaths and serious injuries caused by devices the MDA regime has allowed on the market since 1976 show the limited nature of the Act's reach. In many cases, it has been the tort system, and not the MDA, that protected the public. Indeed, the tort system has functioned as Congress would have expected when it passed the MDA: as a necessary and cost-effective state law complement to the limited federal regime.

Finally, because the circumstances here present a very weak case for preemption, a ruling by this Court that the tort claims at issue are preempted could convince lower courts to hold that similar narrow preemption provisions in other federal consumer protection statutes, including the Consumer Product Safety Act and the Federal Hazardous Substances Act, bar state law tort claims as to the thousands of products regulated under those laws. The result would be a tumultuous gutting of the tort systems of the states and a dramatic restriction of the rights of injured persons — an outcome that the 94th Congress did not authorize or intend.

ARGUMENT

I. THE VAGUE PREEMPTION PROVISION IN THE MEDICAL DEVICE AMENDMENTS CANNOT OVERCOME THE STRONG PRESUMPTION AGAINST PREEMPTING THE TYPE OF STATE LAW AT ISSUE HERE

Jeff Kimbell, executive director of the Medical Device Manufacturers Association, has provided a candid assessment of what this lawsuit is about. "If the Supreme Court affirms the preemption," he told a trade publication, "it could go a long way toward achieving tort reform without a single vote from this

Congress or the next Congress." Hoffman, *Medical Device Liability Case; High Court's Ruling Likely to be Pivotal*, Business Insurance, Jan. 29, 1996, at 2. The phrase "tort reform" normally refers to hotly-contested *legislative* efforts, in statehouses and in the Congress, to alter common law tort doctrines. This case is the culmination of efforts by manufacturers to avoid the legislative process by persuading courts to weaken the tort system through strained readings of federal statutory provisions — to dramatically alter the relationship between consumers and alleged wrongdoers, as well as the relationship between the federal and state governments — without a single vote from any duly-elected legislator.[1]

The Lohrs claim that Lora Lohr was injured by a Medtronic Model 4011 pacemaker lead. Medtronic contends that the MDA preempts the Lohrs' Florida common law tort remedies. The company relies on a provision of the 1976 Act, 21 U.S.C. §360k(a), which bars states from "establish[ing] or continu[ing] in effect" with respect to any medical device "any requirement which is different from, or in addition to, any requirement" in the MDA, if that requirement concerns safety and effectiveness or is otherwise governed by the Act.

The principles of this Court's preemption jurisprudence and underlying principles of federalism and separation of powers require this Court to reject Medtronic's strained interpretation of the Act.

Whether a given state law is preempted pursuant to the Supremacy Clause of the Constitution, U.S. Const. art. VI, cl. 2, is a question of congressional intent. *Hawaiian Airlines, Inc. v.*

---

[1] Manufacturers have been able to achieve far less in Congress than they have under court decisions like the Eleventh Circuit's in this case. The "tort reform" bill passed by the House of Representatives in 1995 would eliminate punitive damages, but not compensatory damages, in suits arising from the use of medical devices that have been approved by the FDA. *See* 141 Cong. Rec. H2941-H2948 (Mar. 9, 1995); 141 Cong. Rec. H3027 (Mar. 10, 1995). The inclusion of this provision indicates that even the "tort reform"-minded House not only believes that all state tort remedies are available with respect to medical devices under current law but also intends, notwithstanding proposed broad changes in tort rules, that such suits continue.

Norris, 114 S. Ct. 2239, 2243 (1994). However, "[c]onsideration under the Supremacy Clause starts with the basic assumption that Congress did not intend to displace state law." *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981). The presumption against preemption is especially strong in this case for three reasons.

First, the state law rules allegedly subject to preemption in this case — common law tort doctrines — are general rules of conduct, not requirements specifically directed at a particular industry. This Court's decisions "have consistently recognized that a congressional intent to deprive the states of their power to enforce general laws is more difficult to infer than an intent to pre-empt laws directed specifically at concerted activity." *New York Telephone Co. v. New York State Department of Labor*, 440 U.S. 519, 533 (1979) (plurality opinion).

Second, the challenged state law rules are in an area of traditional state concern — protecting public health and safety. *Hillsborough County v. Automated Medical Laboratories*, 471 U.S. 707, 715 (1985). Where this traditional and particularly important state authority is at issue, this Court will not find preemption without evidence that preempting state law was "the clear and manifest purpose of Congress." *Id.*

Third, the federal statute involved provides no remedy of the type provided by the state law allegedly preempted — here, damages to compensate individuals for their injuries. In such circumstances, again, this Court has demanded strong proof of congressional intent to preempt. *See English v. General Electric Co.*, 496 U.S. 72, 87-90 (1990); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984); part II.B.3, *infra*.

In light of these factors, this Court should resolve any doubts about the meaning of the federal enactment in favor of the parties arguing against preemption, the Lohrs. There should, in any case, be no serious doubts here. The Lohrs have amply demonstrated that nothing in the MDA provides justification for stripping the states of their historic authority to protect public health and safety by means of the common law.

This Court's requirement of clear and manifest indication of congressional intent to preempt prevents the kind of unwarranted usurpation of state law and individual rights urged by Medtronic. Had Congress made clear to the states that their power to enforce general laws with respect to a broad range of products was to be

so profoundly restricted, they might have used their influence in the political process to protect or restore their authority. Had Congress made clear to advocates for strong health and safety protections, such as *amici*, that it was acting to exempt thousands of potentially hazardous medical devices from the tort liability rules of the states, they would have worked to defeat the offending provisions. They would have done so precisely because the MDA fails to provide the protections and remedies that are available through tort law.

II. THE LIMITED POWERS THE MDA CONFERRED ON THE FOOD AND DRUG ADMINISTRATION INDICATE THAT CONGRESS DID NOT MEAN TO PREEMPT STATE LAW TORT ACTIONS

A. The Primary Purpose of the MDA Was to Enhance Protection of Public Health and Safety

Congress enacted the MDA in 1976, at a time of widespread awareness that rapid advances in biomedical technologies posed not only great promise but also serious safety risks. A 1970 public report by a Nixon Administration commission, established to evaluate the need for greater federal regulation, documented some 10,000 injuries, including 751 fatalities, from medical devices over a ten-year period. These included deaths, miscarriages, birth defects and infections caused by the poorly-designed Dalkon Shield intrauterine device; eye injuries and vision loss from defective intraocular lenses; and deaths and injuries from defective pacemakers. *See* Cooper, *Device Legislation*, 26 Food Drug Cosm. L.J. 165 (1971).

Prior to enactment of the MDA, the FDA had virtually no power to regulate medical devices. The agency had authority under the Federal Food, Drug, and Cosmetic Act ("FDCA") to seize adulterated or misbranded devices, but the process was difficult: The agency could not take action until after a device had been marketed, and it bore the burden of establishing that the device was unsafe or mislabeled. The only way to keep a dangerous device off the market in the first place was to convince a court to treat the device as a "drug." *See* H.R.Rep. 853, 94th Cong., 2d Sess. 8-10 (1976) ("House Report").

The MDA's legislative history demonstrates that the Act's primary purpose was to increase protection of health and safety by enhancing the FDA's authority to prevent the sale of dangerous and ineffective medical devices. *See* House Report, at 1-12; H.R. Conf. Rep. No. 1090, 94th Cong., 2d Sess. 1 (1976); Adler & Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo.L.Rev. 895, 922 n.126 (1994) ("Any fair reading of the legislative history of the Medical Device Amendments will reveal that, except for a few passing references to the need to avoid slowing innovations in medical technology, the critical, and endlessly repeated, focus of congressional attention was to protect consumers from dangerous devices") (citations omitted). The principal Senate sponsor, Senator Kennedy, noted that the MDA "is written so that the benefit of the doubt is always given to the consumer. After all, it is the consumer who pays with his health and his life for medical device malfunctions." 121 Cong. Rec. 10688 (1975).

Given the clear congressional goal of increasing public protection from the dangers of medical devices, it cannot be that Congress meant to strip the states of all of their traditional authority to allow individuals to seek recovery for personal injuries from such devices. In terms of health and safety protection, the MDA's statutory scheme would be a wholly inadequate substitute for the tort system.

B. Federal Authority Under the MDA Did Not and Does Not Provide For Many of the Means of Protection Available Through the Tort System

The common law tort systems of the states have long served crucial functions. Tort remedies allow injured victims to recover damages caused by negligent or intentional wrongdoing. Tort law punishes and deters improper business practices and thereby rewards responsible and ethical behavior in the marketplace. In addition, using the broad civil discovery rules, tort litigation has exposed misconduct and unsafe practices and alerted the media, the public, legislators and regulatory agencies to vital health and safety problems. The tort system has worked particularly well at protecting the public against harmful products, while at the same

time costing government, business and consumers remarkably little.[2] Tort law helps remove from the market products whose dangers are greater than their benefits and deters the sale of such products in the first place.

A Congress concerned about public safety could never have considered the MDA's limited regulatory scheme to be an adequate replacement for state tort systems. FDA powers under the statute do not come close to fulfilling the public protection functions that tort law provides.

1. Limits on Scrutiny of Medical Devices

In deciding whether the 94th Congress could have judged the MDA to be an adequate replacement for tort law in protecting the

---

[2] Contrary to popular myth, product liability claims do not place major economic burdens on business or consumers. Actuary J. Robert Hunter, Federal Insurance Administrator in the Ford and Carter Administrations and later the Texas Insurance Commissioner, now studies liability and insurance issues for *amicus* Consumer Federation of America. In a 1995 report, he found that the total cost of product liability insurance premiums and other product liability costs in 1993 was only 19.9 cents for every $100 in retail sales; in the ten year period from 1984 to 1993, the cost was 26 cents per $100 dollars in sales. Hunter, *Product Liability Insurance Experience 1984-1993* (Consumer Federation of America, Mar. 1995). Hunter told a Senate committee, "The current system of product liability is an exceptional bargain for America: it serves as a deterrent to unsafe products in a free market way, with no bureaucratic regulation, it takes care of persons injured by unsafe products, and it costs remarkably little." Testimony of J. Robert Hunter before the Subcomm. on Admin. Oversight and the Courts of the Senate Comm. on the Judiciary, May 2, 1995. Similarly, a 1995 study by the Risk & Insurance Management Society, Inc., an organization of corporate and non-profit risk managers, and Tillinghast-Towers Perrin, a business consulting firm, found that the cost of "liability risk" — insuring against not only product liability but also other employment discrimination, shareholder suits and other claims — amounted to 25.5 cents for every $100 in revenue in 1994 (a 22 percent drop from the 1993 cost). A *Wall Street Journal* report on the study noted that its "findings are intriguing in light of the widely-held view that American employers are being held hostage by litigation." Wall Street Journal, Dec. 11, 1995, at B5, col. 1.

public against dangerous devices, consider one fact at the outset: Acting in a manner fully consistent with the requirements of the MDA, the FDA specifically evaluates only one percent of new medical devices for safety and effectiveness. And, as discussed below, even the scrutiny that that one percent receives under the Act has been insufficient to keep dangerous products off the market.

The MDA directed the FDA to place each medical device into one of three classes based on level of risk. Class I devices, simple medical tools like bandages, were subject only to general FDA controls applicable to all medical devices, such as labeling requirements and so-called good manufacturing practices. Class II devices, such as syringes and tampons, were, in addition, supposed to meet FDA performance standards.[3] The riskiest devices, such as intrauterine devices and pacemaker components like the one at issue in this case, were to be placed in Class III and, under the MDA, were eventually supposed to undergo a process called pre-market approval ("PMA").

PMA procedures, at least on their face, provide some safety assurance and public disclosure benefits. A manufacturer seeking pre-market approval must conduct both laboratory and clinical studies of the device and submit an application attesting to the device's safety and effectiveness. 21 U.S.C. § 360e(c)(1). The application is reviewed by an FDA panel, which meets in open session, and the agency must release transcripts of the panel meetings, excising only discussions of trade secrets. *Id.* §§ 360e(c)(2), 360j(i). When the FDA, after considering the panel's recommendations, issues its decision, the agency must publish a statement regarding the product's effectiveness and safety, including potential risks. *Id.* § 360j(h)(1). *See* Leflar, *Public Accountability and Medical Device Regulation*, 2 Harv. J.L. & Tech. 1 (1989).

---

[3] The FDA never implemented performance standards for devices, the result of which was that Class II devices were essentially subjected to no more stringent review than Class I devices. In the 1990 Safe Medical Devices Act, *see* part II.B.2, *infra*, Congress eliminated the requirement that the FDA issue performance standards as to each Class II device.

The MDA's PMA process, however, has severe limitations as a protector of public safety. First, it is never required with respect to Class I or Class II devices. Second, it does not impose specific requirements as to the design, manufacture or labeling of any given device. Third, by itself, it does nothing to monitor the safety of devices after they have entered the market.

In addition, the MDA's scheme for PMA review has allowed some remarkably hazardous products onto the market. Take, for example, the "Mini Profile" catheter, made by C.R. Bard, Inc. In May 1988, the FDA approved the catheter through the PMA process. The catheter was to be used in angioplasty, a procedure in which the device is threaded through a patient's body and inflated to clear clogged arteries leading to the heart. Subsequent investigation revealed that no later than February 1988, Bard executives knew that the catheter had a propensity to fail and that such failure could cause death. In March 1988, Bard filed a fraudulent, inaccurate statement with the FDA in support of its PMA application. From July through November 1988, Bard received at least 28 complaints from doctors and others about the Mini Profile's failure to deflate. Bard did not notify the FDA, and the agency apparently did not find out on its own. Bard continued to ship the catheter while launching a secret effort to redesign it.

In December 1988, Eunice Beavers, a resident of Missouri, died during an angioplasty procedure when a Mini Profile catheter failed to deflate, thus blocking her blood flow. Bessie Mae Robinson of Virginia had died in September 1988 under similar circumstances. Boston Globe, Apr. 2, 1994, Economy, at 12; Boston Globe, Oct. 31, 1993, Metro/Region, at 1.[4]

Federal authorities eventually learned of Bard's misconduct from a business competitor. In April 1994, U.S. District Judge Mark L. Wolf accepted an agreement under which the manufacturer pled guilty to 391 felony counts and agreed to pay $61 million in fines, an amount equal to the total revenues Bard

---

[4] Meanwhile, 50 patients had the tip of another Bard catheter, the B Probe, break off inside them during procedures, causing, in some cases, excruciating pain and permanent disability. Authorities later charged that Bard hid from the FDA knowledge that the tips tended to break. *Id.*

had earned on the catheter. *United States v. C.R. Bard, Inc.*, 848 F. Supp. 287 (D. Mass. 1994).

Although the legal system thus eventually punished Bard for its exceptionally egregious misconduct, FDA powers — even when the agency exercised its most stringent review, PMA — were insufficient to keep a dangerous device from entering the market or to detect or expose hazards promptly once it went into use. Nor did the federal statutory scheme provide a dime in compensation to victims, such as the survivors of Eunice Beavers, who saw their state tort claims dismissed on preemption grounds.[5]

The substantial weaknesses in the PMA process, however, are no match for the gross shortcomings, in terms of public protection, of the two provisions by which the MDA has permitted the vast majority of medical devices, including the pacemaker lead at issue in this case, to reach or remain on the market. First, a device in commercial distribution prior to the effective date of the 1976 MDA was "grandfathered" and did not have to go through the PMA process unless and until the FDA classified the device as Class III *and* issued a final regulation calling for PMA applications. *See* 21 U.S.C. §§ 360e(b)(1)(A), 351(f)(2)(B).

---

[5] The family of Eunice Beavers, along with other victims of the defective device, asked Judge Wolf to order restitution in the criminal proceeding. He declined, holding that it would be too time-consuming and complicated to litigate fault for injuries in connection with criminal sentencing. He added that civil suits were a much more appropriate means for redressing injuries because, in contrast to a criminal restitution proceeding, damages for pain and suffering and punitive damages might be available. 848 F. Supp. at 292-93.

Four months later, Judge Wolf himself dismissed the civil suit brought by the Beavers family. He concluded, based on First Circuit precedent brought to his attention by Bard, that their claims were preempted by the MDA. The First Circuit affirmed. *Talbott v. C.R. Bard, Inc.*, 865 F. Supp. 37 (D.Mass. 1994), *aff'd*, 63 F.3d 25 (1st Cir. 1995), *petition for cert. filed*, Feb. 16, 1996, No. 95-1321.

The FDA did eventually issue a recall of the Mini-Profile catheter and imposed civil fines on Bard, but it did so under authorities Congress provided in 1990. *See* part II.B.2, *infra*. The 1976 MDA, the legislation that Medtronic contends preempted state tort law, did not allow for even these protections.

Second, under the so-called 510(k) procedure, a new device can enter the market promptly, without FDA safety review, if it is "substantially equivalent" to a "grandfathered" device or a substantially equivalent device already on the market, or if it is a Class I or Class II device. 21 U.S.C. § 360c(f)(1)(A). Because the 510(k) notification process is far less elaborate and far less expensive than the PMA application process, and because the FDA has yet to issue final PMA regulations for most Class III devices, 510(k) clearance has become the overwhelmingly dominant means of market entry: Notifications under section 510(k) account for 80 percent of Class III devices on the market and 99 percent of all medical device submissions. H.R. Rep. 808, 101st Cong., 2d Sess. 14, *reprinted in* 1990 U.S.C.C.A.N. 6307; Testimony of FDA Commissioner David A. Kessler before the Senate Comm. on Labor and Human Resources, Apr. 6, 1995.

The "grandfathering" and 510(k) procedures require no FDA evaluation of whether a device is safe or effective. *See* 21 U.S.C. § 360c(f)(1); 21 C.F.R. § 807.100 (b). The procedures also totally fail as means of providing public information about medical devices. The 510(k) process is "a black box, entirely shielded from ... public scrutiny." Leflar, 2 Harv. J.L. & Tech. at 34. There is no advisory panel, no reported record, no statement of reasons, and no opportunity provided by statute to challenge the marketing clearance administratively or in court. *Id.*

Although there is no evidence that the 94th Congress intended the 510(k) process to become the dominant means by which Class III medical devices would enter the market in the long term, Congress certainly had to expect a substantial transition period — while the agency worked to classify devices and review PMA applications — during which this process would play the central role and in which many grandfathered devices would remain on the market. Moreover, nothing in the 1976 Act imposed time tables for implementation of PMA requirements or otherwise prevented the FDA from relying indefinitely on 510(k) procedures to clear most devices, including Class III devices, for marketing. In light of the evidence documented by the Nixon Administration's 1970 report and the crisis over the Dalkon shield, it is wholly implausible that Congress, in the process of enacting a law aimed at increasing public protection, would have meant to abolish all tort remedies *immediately* on the effective date of the Act —

thereby leaving the public with virtually no protection, not even the modest requirements of the PMA process, for an indefinite period.

2. Limits on FDA Enforcement Authority

Even assuming that Congress intended a relatively rapid transition, after which the vast majority of Class III devices would be subject to pre-market approval, the MDA would still have lacked many of the important public protection benefits provided by the tort system with respect to any medical device.

First, again, under the MDA, pre-market approval procedures are never required for Class I and Class II devices.

Second, the 1976 Act did not provide the FDA with adequate authority to investigate industry practices. In particular, the 1976 Act did not provide, nor did prior law grant, subpoena power to the FDA to compel the disclosure of documents or the testimony of witnesses relating to medical devices. By contrast, the civil discovery rules that govern tort litigation in state and federal courts permit plaintiffs broad authority to obtain, by court order if necessary, records and other physical evidence as well as the appearance of witnesses. *See, e.g.*, Fed.R.Civ.P. 26(b)(1), 37.

Nor did the MDA, as enacted, establish effective procedures for monitoring FDA-approved medical devices *after* they had entered the market. *See* Leflar, 2 Harv. J.L. & Tech. at 78-82; Adler, *The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction*, 43 Food Drug Cosm. L.J. 511, 518-519 (1988). This shortcoming reduced substantially the MDA's effectiveness in deterring improper practices by manufacturers. The tort system, of course, operates precisely by providing such post-market scrutiny.

Nor did the 1976 Act give the FDA sufficient means to order the recall of a defective device. Although the Act provided the FDA with the technical authority to compel repair, replacement, or refund with respect to medical devices, 21 U.S.C. § 360h(b)(1), substantive and procedural hurdles written into the Act itself

prevented the agency from ever exercising this authority.[6] Nor did the 1976 Act authorize the FDA to impose civil penalties in order to deter and punish misconduct.

In its brief, Medtronic contends that "[u]nder the MDA, the FDA ... has broad enforcement power." Brief for Petitioner Medtronic at 6-7. Yet many of the FDA authorities that Medtronic cites to support that proposition are nowhere to be found in the 1976 MDA, the statute whose meaning is before this Court. These include the power to issue cease-and-desist orders barring the distribution and use of dangerous devices, 21 U.S.C. § 360h(e)(1)(A), to order the recall of devices, *id.* § 360h(e), and to impose civil penalties for violations of the FDCA with respect to devices, *id.* § 333(g)(1)(A). These provisions enhancing FDA authority were actually added fourteen years after passage of the MDA when Congress enacted the 1990 Safe Medical Devices Act, P.L. No. 101-629, 104 Stat. 4511 (codified in various sections of 21 & 42 U.S.C.) (the 1990 Act). The 1990 Act also expanded the FDA's duty to order manufacturers to notify doctors and hospitals regarding dangerous devices (another authority Medtronic cites), 21 U.S.C. § 360h(e)(1)(B), and granted the FDA new authority to issue subpoenas for witnesses and evidence in investigations regarding the assessment of civil penalties, *id.* § 333(g)(2)(A), and to require post-market surveillance of devices when necessary to protect the public, *id.* § 360*l*

---

[6] To justify such a remedy the FDA was required to show not only that the device posed "an unreasonable risk of substantial harm to the public," but also that there were reasonable grounds to believe that the device was not properly designed and built in light of the state of the art at the time of such design and manufacture. This "state of the art" requirement created problems of proof for the FDA, and it kept the Agency from acting with respect to even concededly defective medical devices. *See* Staff of Subcomm. on Oversight and Investigations, Comm. on Energy and Commerce, *The Bjork-Shiley Heart Valve: "Earn As You Learn"; Shiley Inc.'s Breach of the Honor System and FDA's Failure in Medical Device Regulation*, Comm. Print 101-R, 101st Cong., 2d Sess. 5 (1990). The weak authority provided by this MDA provision not only prevented FDA formal action; it also weakened the Agency's hand in negotiating voluntary recalls by manufacturers. Adler, 43 Food Drug Cosm.L. J. at 530.

The strengthening provisions in the 1990 Act underscore the 1976 law's total inadequacy as a replacement for the tort system in protecting the public against hazardous devices: to start with, no civil penalties, no subpoena power, no effective post-market monitoring, and no effective recall power. Otherwise, the 1990 strengthening provisions are of little relevance to the Court's central inquiry: What does the 1976 MDA's preemption provision mean? Because the 94th Congress gave the FDA relatively weak authority to regulate medical devices, *even in tandem with state tort law*, as the 101st Congress apparently concluded, this Court should not lightly infer that the 94th Congress meant to preempt all tort remedies.

In any case, even after the 1990 amendments, Congress could not have considered the FDA system an adequate substitute for the tort system. The 1990 amendments have done little if anything thus far to steer new device clearances away from the hands-off 510(k) process. In addition, the civil fines that the FDA is now permitted to impose (a maximum of $15,000 for each violation and $1 million for all violations in a single proceeding) are small in comparison to potential damages resulting from dangerous devices affecting thousands of people. Such fines may well be insufficient to deter violations where lucrative opportunities arise in the medical device field. [7]

---

[7] Neither the 1990 Act nor its legislative history indicate that the 101st Congress believed that federal law preempted state tort claims concerning medical devices. Indeed, at the time the Safe Medical Devices Act was enacted in November 1990, most, if not all, courts that had considered the issue of MDA preemption of tort law found preemption, if at all, only with respect to claims regarding the adequacy of warnings in cases involving tampons whose packages included specific warning language mandated by the FDA. *See, e.g., Moore v. Kimberly-Clark Corp.*, 867 F.2d 243 (5th Cir. 1989). It was not until 1992 that any appellate court found that the MDA had more general preemptive effect. *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir.), *cert. denied*, 113 S.Ct. 327 (1992).

3. Lack of Damage Remedies

Finally, nothing in the 1976 Act or elsewhere in the federal regulatory scheme, even after the 1990 amendments, permits victims of defective medical devices, or their survivors, to obtain compensation for personal injuries. The MDA does not authorize individual damage suits, and the courts have not implied a private right of action. *See, e.g., Bailey v. Johnson*, 48 F.3d 965, 967-68 (6th Cir. 1995).[8]

This Court faced a similar situation in *Silkwood v. Kerr-McGee Corp.* There the survivors of Karen Silkwood sought damages in tort against the operator of a nuclear power plant for Silkwood's contamination by plutonium. Although this Court acknowledged that Congress had intended to occupy the "entire field of nuclear safety concerns, except the limited powers expressly ceded to the states," 464 U.S. at 251 (citing *Pacific Gas & Elec. Co. v. Energy Resources Conserv. & Dev. Comm'n*, 461 U.S. 190, 212 (1983)), it ruled that the Silkwood family's tort action was not preempted. What this Court said in that case is apt here: "It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct." *Id.*

It is particularly difficult to believe here that Congress would have taken the radical step of preempting tort remedies — granting manufacturers immunity — with respect to one category of products, medical devices, without providing any explanation whatsoever as to why medical devices in particular were entitled to such exemption. The public, organizations concerned with public health and safety, and, indeed, manufacturers, would have wanted to know the basis on which Congress was exempting

---

[8] The weak repair, replacement and refund provision in the 1976 Act, *see* fn. 6, *supra*, had it ever been used, apparently would have allowed victims to recover only the purchase price of a defective device. Thus, under this provision, alleged victims of the Dalkon shield, including at least 18 women who died and thousands who suffered infections, became infertile, or bore severely handicapped children, *see* Washington Post, Apr. 7, 1985, at A1; N.Y. Times, Aug. 1, 1984, at D1, col. 3, would have been entitled to receive back from the A.H. Robins Company only what they paid for the Dalkon Shield — less than $100.

medical devices from product liability rules without doing the same for other products, such as foods, drugs and cosmetics, which had long been regulated under the same statute and by the same federal regulatory agency.

The limited preemption of tort remedies recognized by this Court in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), does not call into question this Court's conclusion in *Silkwood* that it is inappropriate to infer, without explicit evidence, a congressional intent to eliminate all remedies for persons claiming injury from some category of harm. This Court's decision in *Cipollone* did not provide cigarette makers with blanket immunity from most or all theories of tort liability — as the power plant operator urged in *Silkwood* and Medtronic urges here — or even from any particular type of tort claim. Instead, Justice Stevens' plurality opinion carefully interpreted the preemption clause of the Public Health Cigarette Smoking Act of 1969 to bar only certain aspects of some of the tort claims brought by the son of a deceased smoker against tobacco companies.

The *Cipollone* plurality reached a plausible result: Congress had mandated precise warnings about the health effects of smoking on cigarette packages and advertising. The applicable preemption clause, barring any further state "requirement or prohibition based on smoking and health ... with respect to the advertising or promotion of any cigarettes," meant that cigarette makers could not be expected to say more about the health effects of smoking in those particular forums. The states were thus prohibited, through tort law or otherwise, from penalizing cigarette makers for failing to provide additional warnings in those places. Thus the plurality recognized that Congress meant to establish uniform package and advertisement warnings. After *Cipollone*, victims of smoking remain free to seek damages against tobacco makers under all state tort theories. They are barred only from basing a claim of failure to warn or fraudulent representation, in whole or in part, on a manufacturer's failure to place additional warnings on cigarette packages or advertisements. Plaintiffs may continue to argue that manufacturers should have provided additional health warnings in other forums or that manufacturers made false statements about the health effects of their products, either on packages or advertisements or elsewhere. *See* 505 U.S. at 524-30 (plurality opinion).

C. Inadequate Funding of the FDA from the 94th Congress to the Present Has Further Weakened the Capacity of the Agency to Ensure Health and Safety

The Lohrs' position — that the provisions of the MDA cannot be read to direct that the FDA regulatory system replace the tort system — is bolstered by the fact that the 94th Congress and its successors have never provided the agency with sufficient funds to meet even the limited mandate of the MDA.

It is widely accepted that the FDA has lacked and still lacks the financial resources to evaluate carefully and efficiently the products of the some 7000 medical device makers, particularly Class III devices. See Adler, 43 Food Drug Cosm. L.J. at 530; Subcomm. on Oversight and Investigations, Comm. on Energy and Commerce, *Less Than the Sum of Its Parts; Reforms Needed in the Organization, Management, and Resources of the Food and Drug Administration's Center for Devices and Radiological Health*, Committee Print 103-N, 103d Cong., 1st Sess. 9, 14 (1993) ("Less Than the Sum"); N.Y. Times, Aug. 8, 1982, sec. 4, at 7, col. 1 ("[FDA Bureau of Medical Devices] personnel say they are overwhelmed by the number and kinds of medical devices and products they must regulate. A staff of 707 and a $28 million budget, they say, pale when faced with some 1,800 [types of] medical devices now on the market that require classification and another 43,000 products that must be registered").[9] If Congress had genuinely intended the MDA to provide the only legal protections against dangerous medical devices, Members in favor of strong health and safety protection, not to mention consumer organizations, would have treated Congress's failure to fund the Act's enforcement as a very grave matter.

Congress's failure to provide sufficient resources to cope with the rapid development of medical devices has kept the FDA where

---

[9] In recognition of the fact that annual appropriations have been insufficient even to fund the limited review provided by the MDA, FDA Commissioner Kessler is now seeking authority from Congress to require medical device manufacturers to pay fees for pre-market reviews under both PMA and 510(k) procedures. Testimony of FDA Commissioner Kessler, Apr. 6, 1995.

the 1976 Act permits the agency to remain: in the thrall of the relatively quick, inexpensive and industry-preferred 510(k) procedure. Because of the abbreviated nature of the 510(k) process, "the agency's main source of information to assess the safety and effectiveness of devices before they reach users is the [good manufacturing practices] inspection process." U.S. General Accounting Office, *Medical Technology: Quality Assurance Needs Stronger Management Emphasis and Higher Priority* 2 (GAO/PEMD-92-10 Feb. 1992). But FDA efforts in this area, too, have been weakened by funding shortfalls: When a 1992 General Accounting Office study found that the agency had failed to inspect many device makers for substantial periods, *id.*, the FDA responded that it was hampered by limited resources. *Id. at* 92-96.

To conclude that the 94th Congress meant to take the radical step of preempting state tort law with respect to medical devices, this Court would have to find that although Congress said one thing — it wanted to protect the public against harmful medical devices — it in fact intended another — to eliminate tort liability for medical devices and replace that system with limited federal enforcement authority and funding insufficient to carry out even that authority. Of course, it is possible, though there is not a single piece of evidence, that some Members of Congress had, but concealed, such a cynical motivation as they crafted the 1976 legislation. But such speculation is no substitute for the clear evidence that this Court has always required in order to find preemption of matters historically governed by the states.[10]

---

[10] Representative Henry Waxman, a member of the Subcommittee on Health and the Environment of the House Commerce Committee at the time of passage of the 1976 Act (and later chairman of the subcommittee) and a supporter of the Act, for one, did not detect such cynicism among his colleagues:

> I can assure you that it was never my intent that the Medical Device Amendments preempt state product liability laws in any way. Nor am I aware of any person who was a Member of Congress in 1976 who intended such preemption. Certainly, preemption of State product liability laws would have been a significant issue, which would have engendered significant opposition if the Members had thought the law could have

III. THE MANY CASES OF SEVERE INJURY CAUSED BY MEDICAL DEVICES SINCE 1976 SHOW THE LIMITED NATURE OF THE FDA'S AUTHORITY AND UNDERSCORE THAT CONGRESS DID NOT MEAN TO PREEMPT STATE TORT SUITS

A. The Tort System Has Functioned As Congress Envisioned When It Passed the MDA: As a Necessary Complement To Federal Authority

That Congress never meant the FDA's limited regulatory authority to become the sole guardian of public safety with respect to medical devices is supported by evidence from the real world. There have been many cases in addition to the Bard catheter case discussed in part II.B.1, *supra*, in which medical devices put on the market with the FDA's blessing — some through the 510(k) process, others through the pre-market approval process — caused severe harm to individuals. In most cases, the public was protected only through the tort system.

For 20 years, the tort system has worked in tandem with the limited system of regulation established by the MDA to improve public health and safety, punish wrongdoing, and reward responsible business conduct.[11] Tort actions have provided the only means to compensate victims for their personal injuries. Moreover, for 15 years after Congress enacted the MDA, tort suits also provided the only means to make irresponsible manufacturers pay any civil financial penalties for misconduct. Thus, tort law has been the primary mechanism for deterring the manufacture and

---

been interpreted in this way.
Letter from Representative Henry A. Waxman to Robert Steinberg (Aug. 10, 1993), reproduced in *Talbott v. C.R. Bard, Inc.*, No. 95-1321, Petition for Writ of Certiorari at Appendix M, 94a-95a.

[11] MDA procedures can assist responsible companies in avoiding potential liability. Indeed, *amici* do not contend that juries cannot or should not weigh evidence of compliance with FDA requirements and procedures in considering whether a company acted reasonably. This case is about whether victims of dangerous medical devices will have the opportunity to present their claims at all.

sale of dangerous medical devices. And information obtained and brought to public attention through tort litigation has been crucial in informing the marketplace and spurring the FDA to take necessary action.

As the following cases show, and as Congress knew in 1976, the powers conferred under the MDA are insufficient to permit the FDA to do the job alone.

B. The Bjork-Shiley Heart Valve

Surgeons implant mechanical heart valves to replace patients' diseased or deformed valves. The FDA approved the Bjork-Shiley convexo-concave heart valve through the MDA's pre-market approval process in April 1979. During clinical trials, one of the valves had fractured. The manufacturer, Shiley, Inc., called the incident an anomaly, although it knew of other such fractures. A 1990 report by FDA staff members found that Shiley gained FDA approval for the device by withholding material information regarding the defect. It also concluded that Shiley engaged in repeated efforts to obstruct FDA investigation and keep the device on the market. Johnson, *et al.*, Report of the Shiley Task Group (Dec. 1990); *see* Less Than the Sum, *supra*, at 21.

In January 1984, despite confirmation of 73 fractures causing 58 deaths, the FDA decided not to seek a recall of the valves; instead the agency asked Shiley for more data. After receiving limited data, the FDA decided, in July 1984, to take no action. *Id.* at 28. FDA officials, according to a congressional staff report, explained that the agency had not invoked its recall (repair/replace) authority under the 1976 Act because that authority was "so lengthy and difficult to sustain in court that it has never been used." *Id.* at 5. The authorities provided by the MDA not only failed to keep the defective valves of the market; they also prevented the FDA from acting even in the face of clear evidence of injury.[12]

---

[12] Bjork-Shiley heart valve recipients live with fear. A recent article described the ordeal of Elaine Levenson, the founder of *amicus* VALV:

> Elaine Levenson lies in bed each night listening to the clicking of the artificial valve implanted in her heart. As long

About 40,000 people in the United States received the valves before Shiley removed them from the market in 1986. By 1990, at least 389 valves had fractured, resulting in 248 deaths. Staff of Subcomm. on Oversight and Investigations, Comm. on Energy and Commerce, *The Bjork-Shiley Heart Valve: "Earn As You Learn"; Shiley Inc.'s Breach of the Honor System and FDA's Failure in Medical Device Regulation*, Comm. Print 101-R, 101st Cong., 2d Sess. 2 (1990).

The tort system offered the only effective response. Litigation, including a 1992 class action settlement against Shiley and its corporate parent, Pfizer, provided some financial redress for the surviving valve recipients. *See Bowling v. Pfizer*, 143 F.R.D. 141 (S.D. Ohio 1992).[13]

> as she hears that sound, she knows her Bjork-Shiley heart valve hasn't malfunctioned. Levenson has lived for five years now with the knowledge that the implant could fracture at any moment.....
>
> Fear has changed every aspect of Levenson's life. She used to walk six miles a day and play tennis, but she has stopped exercising because she's afraid it might strain her implant. She doesn't like to stay alone with her grandchildren, because they wouldn't know what to do if her device broke.... Her cardiologist says she will know instantly if the valve malfunctions. "It will be the mother of all pain," he has told her....
>
> Several surgeons have advised Levenson against removing her ... valve on the grounds that she might die during open-heart surgery.... [A]t 57, she feels trapped. "I'd rather take the risk of lying on an operating table now, because at least I'd have a chance," says Levenson. "The hardest thing is being so scared all the time. It's very stressful living with a time bomb inside you and not knowing when it's going to blow."

Green, *Dangerous Devices; Artificial Implants*, American Health, Jan. 1995, at 68.

[13] More recently, Shiley has contended that the MDA preempts tort claims. *See, e.g., Michael v. Shiley*, 46 F.3d 1316 (3rd Cir. 1995) (finding some, but not all, claims preempted), *cert. denied*, 116 S.Ct. 67 (1995).

C. The Vitek Jaw Implant

Vitek, Inc., developed a jaw implant made of Teflon for persons suffering from a painful condition called temporomandibular joint disorder. Vitek's implants entered the market through the MDA's 510(k) substantial equivalence process; there was no FDA review of safety or effectiveness. Between 1983 and 1990, more than 26,000 people received the implants. What they did not know was that Vitek had never tested the product in animals or humans before the implants were marketed. Experience showed that the devices tended to fragment, leading to deterioration of the skull and debilitating pain. In 1988, Vitek, under the pressure of hundreds of lawsuits filed by patients (total claimants eventually reached 3,000), stopped selling its defective implants. Only after these developments did the FDA, in 1990, issue a safety alert. *See* Connelly, *Jaw Implant Suit Takes the Fast Track*, Texas Lawyer, July 17, 1995, at 6; Boston Globe, June 5, 1992, at 11; N.Y. Times, June 5, 1992, at A14, col. 2.

D. Playtex Super-Absorbent Tampons

Betty O'Gilvie, a Kansas woman, died in 1983 from toxic shock syndrome after using Playtex super-absorbent tampons. The MDA had not required Playtex to demonstrate the safety or effectiveness of these tampons: Implementing the MDA's provisions, the FDA had classified tampons as Class II devices. As such, tampons were subject only to performance standards — standards the agency never issued.

As the Tenth Circuit Court of Appeals later found, there was "abundant evidence that Playtex deliberately disregarded studies and medical evidence linking high-absorbency tampon fibers with increased risk of toxic shock at a time when other manufacturers were responding to this information by modifying or withdrawing their high-absorbency products." *O'Gilvie v. International Playtex, Inc.*, 821 F.2d 1438, 1446 (10th Cir. 1987), *cert. denied*, 486 U.S. 1032 (1988). The court also noted "evidence that Playtex deliberately sought to profit from this situation by advertising the effectiveness of its high absorbency tampons ...." *Id.* In 1985, a federal jury awarded O'Gilvie's family $1.5 million in compensatory damages and $10 million in punitive damages.

Playtex promptly removed the tampons from the market, improved its warnings on other products about toxic shock syndrome, and began an effort to increase public awareness of the problem. The trial judge remarked that the suit had "literally changed an industry." Bates, *TSS Award Slashed After Playtex Stops Selling Tampon*, The National Law Journal, June 10, 1985, at 10.

E. The Airco Ventilator

Airco, Inc., sold a ventilator that assisted patient breathing during surgery. The family of Georgia Huchingson, an Arkansas woman, sued the company after she suffered brain and lung damage as a result of being connected to the device during a May 1980 operation; she died in January 1982. A jury concluded that the ventilator was defectively designed because it included a switch that made it easy for operators to inadvertently misuse the machine, resulting in oxygen deprivation to the patient. The Arkansas Supreme Court, upholding an award of punitive damages against Airco (the first time that court had approved a punitive damages award in a product liability suit), ruled that Airco "knew from the outset, by its very own testing, that an unnecessary component of the product was so deadly that it should never have been made available to the public." *Airco, Inc. v. Simmons First National Bank*, 638 S.W.2d 660 (Ark. 1982). As a result of the family's victory in court, Airco voluntarily issued a medical device alert through the FDA, warning physicians and hospitals of the potential danger.

F. Orcolon Eye Gel

Orcolon eye gel, manufactured by Optical Radiation Corporation (ORC), was designed to steady the eyeball during cataract surgery. The gel was supposed to dissipate immediately after surgery. In clinical trials of the product, however, it failed to do so and created dangerously high eye pressure, requiring at least two patients to undergo emergency surgery to prevent blindness. Nevertheless, the agency approved Orcolon through the PMA process in March 1991. Soon after, doctors began reporting cases of increased pressure and loss of sight. By the time ORC, at FDA's request, withdrew the gel in October 1991, the product

had caused total or partial blindness in at least 100 people. By March 1992, there were over 270 reports of adverse reactions. Less Than the Sum, *supra*, at 30; Green, *Dangerous Devices; Artificial Implants*, American Health, Jan. 1995, at 68. Once again, PMA procedures were simply inadequate to prevent or redress harm.

G. Silicone Breast Implants

Since the 1960's, an estimated one million women in the United States have received gel-filled silicone breast implants, some for cosmetic enhancement and others for reconstruction following mastectomy. There has been enormous controversy over claims that the implants cause connective tissue disorders. Major ongoing studies, including one at the National Institutes of Health, may help resolve the dispute.[14] It is already clear, however, that the implants tend to rupture, causing silicone gel to leak into the bodies of recipients. Citing published studies, FDA Commissioner David A. Kessler has stated that the "rupture and bleed rate is somewhere between 5 and 71 percent." *Nightline* (ABC television broadcast, Aug. 17, 1995). Leakage can cause pain and swelling. Id.

Breast implants were grandfathered when the MDA was enacted in 1976, and models developed thereafter were marketed pursuant to section 510(k). The FDA took no action until 1988, when it classified silicone implants as Class III devices. The agency called for pre-market approval applications in 1991. *See* Less Than the Sum, *supra*, at 25; Testimony of FDA Commissioner David A. Kessler before the House Subcomm. on Human Resources and Intergovernmental Relations, Comm. on Government Reform and Oversight, Aug. 1, 1995.

By then, lawsuits brought by implant recipients, and not FDA review, had exposed deficiencies in the devices. In particular,

---

[14] The largest completed study to date, partly funded by implant makers and directed by a Harvard Medical School epidemiologist, found that women with breast implants were 24 percent more likely to report connective tissue diseases than women without implants. Washington Post, Feb. 28, 1996, at A13.

discovery in tort litigation had, by the early 1980's, unearthed internal corporate records showing that officials at Dow Corning, the dominant maker of the implants, had done insufficient testing to ensure the long-term safety of the devices and had long been aware that the implants tended to leak and that silicone posed risks for the human body. *See* Frankel, *From Pioneers to Profits*, The American Lawyer, June 1992, at 82; Washington Post, Mar. 3, 1992, at Z10. Only after litigation opened the manufacturers' files did the FDA, on January 6, 1992, request a voluntary moratorium on the use of silicone gel implants pending further review. The agency subsequently restricted use of the implants to patients participating in clinical investigations and research studies.

H. Pedicle Screws

In the early 1980's, some surgeons began using bone screws in spinal fusion surgery. Implanted in narrow archways in the spine called pedicles, the devices attach metal plates to patients' vertebrae. The FDA allowed marketing of the screws, through the 510(k) process, for use in arm and leg bones. But the agency, concerned about the proximity of the screws to the spinal canal and nerve roots, approved only clinical testing of the pedicle procedure.

Nevertheless, and unlawfully, manufacturers began to promote the screws for general use in the spine. Since the mid-1980's, the screws have been implanted in the spines of some 300,000 people. Patients have suffered a range of adverse results, including intense chronic pain, loss of sensation in the legs, and sexual dysfunction.

Instead of seeking to punish the manufacturers, the FDA is now proposing that controls on the screws be loosened by downgrading them from Class III to Class II. The agency has also granted 510(k) marketing clearance for some pedicle screws.

Tort litigation, meanwhile, has unearthed vital information, some that the FDA had never obtained (and some that the agency had obtained but never acted on). A lawsuit involving over 3,000 claimants, *In Re: Orthopedic Bone Screw Product Liability Litigation*, M.D.L. Docket No. 1014 (E.D.Pa.), has revealed that companies falsified data and marketed the screws for use in the pedicles without any animal or human testing; that surgeons

promoted the use of the screws while receiving stock options from their manufacturers; that the FDA relied on studies prepared by some of those same surgeons; and that a consulting firm had, on the advice of its counsel, systematically implemented what the trial judge has termed a document "destruction policy" with respect to records associated with one of the FDA studies. *See* MacLachan, *Bone Screw Suit Places FDA in 4-Way Squeeze*, The National Law Journal, Jan. 8, 1996, at A1. Once again, it is the tort system, and not MDA procedures, that is bringing to public attention information crucial to allowing an informed decision on medical devices. But manufacturers are seeking to halt the litigation and further disclosures by arguing that the MDA preempts the plaintiffs' claims. *Id.*[15]

IV. A FINDING OF PREEMPTION HERE WOULD OPEN THE FLOODGATES FOR DEMANDS FOR JUDICIALLY-CREATED TORT IMMUNITY

As the Lohrs have persuasively argued, the fact that this Court in *Cipollone* concluded that the phrase "requirement or prohibition," in the context of the Public Health Cigarette Smoking Act of 1969 encompassed common law tort actions does not compel the conclusion that the word "requirement" in section 360k(a) of the MDA does the same. However, if this Court does find preemption in this case, it may be difficult for lower courts across the country to avoid the conclusion that other federal

---

[15] The Bard catheter, Bjork-Shiley valve, and pedicle screw cases are not the only major ones in which courts, citing federal preemption, are now dismissing tort claims alleging injuries from medical devices. Other cases involve injuries caused, for example, by allegedly defective penile implants (510(k) devices), *see Duvall v. Bristol-Myers-Squibb Co.*, 65 F. 3d 392 (4th Cir. 1995), *petition for cert. filed*, Dec. 22, 1995, No. 95-1010; *English v. Mentor Corp.*, 67 F.3d 477 (3d Cir. 1995), *petition for cert. filed*, Dec. 26, 1995, No. 95-1034; and injectable collagen (PMA device), which has been used to treat wrinkles and acne but has been linked to autoimmune diseases, *see King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S.Ct. 84 (1993); *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. denied*, 114 S.Ct. 86 (1993).

statutes with preemption provisions that include the word "requirement," regardless of the context in which the word is used, preempt a range of other tort claims. Indeed, preemption provisions in the Consumer Product Safety Act ("CPSA") and the Federal Hazardous Substances Act ("FHSA") are quite similar to that in the MDA.[16] That courts may begin to find that those

---

[16] The MDA's main preemption provision, 21 U.S.C. § 360k (a), provides in relevant part:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement —
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

A preemption provision in the FHSA, 15 U.S.C. § 1261 note, as amended, relating to dangerous toys and household products, states in relevant part:

> [I]f under the regulations of the Commission ... a requirement is established to protect against a risk of illness or injury associated with a hazardous substance, no State or political subdivision of a State may establish or continue in effect a requirement applicable to such substance and designed to protect against the same risk of illness or injury unless such requirement is identical to the requirement established under such regulations.

The preemption provision in the CPSA, 15 U.S.C. § 2075, as amended, states in relevant part:

> Whenever a consumer product safety standard under this Chapter is in effect and applies to a risk of injury associated with a consumer product, no State or political subdivision of a State shall have any authority either to establish or to continue in effect any provision of a safety standard or regulation which prescribes any requirements as to the performance, composition, contents, design, finish, construction, packaging, or labeling of such product which are designed to deal with the same risk of injury associated with such consumer product, unless such requirements are identical to the requirements of the Federal standard.

statutes, too, preempt common law is not idle speculation. *See, e.g., Moe v. MTD Products, Inc.*, 73 F.3d 179 (8th Cir. 1995) (CPSA preempts claims for strict liability, negligence, and breach of implied warranties arising when 17-year-old boy's fingers amputated by lawnmower). Thus, a decision by this Court in favor of Medtronic could indeed effect extraordinarily significant nationwide tort "reform," eliminating consumer remedies with respect to thousands of consumer products, without a single purposeful legislative vote.

CONCLUSION

For the foregoing reasons, *amici* urge the Court to affirm the Eleventh Circuit insofar as that court held that federal law did not preempt the Lohrs' common law claims and reverse the Eleventh Circuit insofar as it found federal preemption.

Respectfully submitted,

DAVID HALPERIN
Counsel of Record
2027 Massachusetts Avenue, NW
Washington, D.C. 20036
(202) 328-2232

Counsel for *Amici Curiae*

March 13, 1996

The CPSA and FHSA, like the MDA, permit States and their subdivisions to petition federal regulators for permission to enact more stringent safety requirements — a procedure that has no relevance to common law tort rules. *See* Brief for Cross-Petitioners Lora Lohr and Michael Lohr at 23-27.